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See OMB statement on reverse

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page ____ of ____

Mfr report #

UF/Dist report #

FDA Use Only

A. Patient information

1. **Patient identifier**
In confidence

2. **Age at time of event:**
or
Date of birth:

3. **Sex**
☐ female
☐ male

4. **Weight**
_____ lbs
or
_____ kgs

B. Adverse event or product problem

1. ☐ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)

2. **Outcomes attributed to adverse event** (check all that apply)
☐ death _____ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: _____

3. **Date of event** (mo/day/yr)

4. **Date of this report** (mo/day/yr)

5. **Describe event or problem**

6. **Relevant tests/laboratory data**, including dates

7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. **Name** (give labeled strength & mfr/labeler, if known)
#1
#2

2. **Dose, frequency & route used**
#1
#2

3. **Therapy dates** (if unknown, give duration)
from/to (or best estimate)
#1
#2

4. **Diagnosis for use** (indication)
#1
#2

5. **Event abated after use stopped or dose reduced**
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. **Lot #** (if known)
#1
#2

7. **Exp. date** (if known)
#1
#2

8. **Event reappeared after reintroduction**
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. **NDC # –** for product problems only (if known)
– –

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

D. Suspect medical device

1. **Brand name**

2. **Type of device**

3. **Manufacturer name & address**

4. **Operator of device**
☐ health professional
☐ lay user/patient
☐ other: _____

5. **Expiration date** (mo/day/yr)

6.
model # _____
catalog # _____
serial # _____
lot # _____
other #

7. **If implanted, give date** (mo/day/yr)

8. **If explanted, give date** (mo/day/yr)

9. **Device available for evaluation?** (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on _____ (mo/day/yr)

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

E. Initial reporter

1. **Name, address & phone #**

phone #

2. **Health professional?**
☐ yes ☐ no

3. **Occupation**

4 **Initial reporter also sent report to FDA**
☐ yes ☐ no ☐ unk

PLEASE TYPE OR USE BLACK INK

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

FDA Form 3500A (1/96)

Medication and Device Experience Report

(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

FDA Use Only

F. For use by user facility/distributor–devices only

1. **Check one**
☐ user facility ☐ distributor

2. **UF/Dist report number**

3. **User facility or distributor name/address**

4. **Contact person**

5. **Phone Number**

6. **Date user facility or distributor became aware of event** (mo/day/yr)

7. **Type of report**
☐ initial
☐ follow-up # ____

8. **Date of this report** (mo/day/yr)

9. **Approximate age of device**

10. **Event problem codes** (refer to coding manual)
patient code ____ – ____ – ____
device code ____ – ____ – ____

11. **Report sent to FDA?**
☐ yes ____ (mo/day/yr)
☐ no

12. **Location where event occurred**
☐ hospital
☐ home
☐ nursing home
☐ outpatient treatment facility
☐ outpatient diagnostic facility
☐ ambulatory surgical facility
☐ other: ____ specify

13. **Report sent to manufacturer?**
☐ yes ____ (mo/day/yr)
☐ no

14. **Manufacturer name/address**

G. All manufacturers

1. **Contact office – name/address** (& mfring site for devices)

2. **Phone number**

3. **Report source** (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☐ health professional
☐ user facility
☐ company representative
☐ distributor
☐ other: ____

4. **Date received by manufacturer** (mo/day/yr)

5. (A) NDA # ____
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

6. **If IND, protocol #**

7. **Type of report** (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☐ periodic
☐ Initial ☐ follow-up # ____

8. **Adverse event term(s)**

9. **Mfr. report number**

H. Device manufacturers only

1. **Type of reportable event**
☐ death
☐ serious injury
☐ malfunction (see guidelines)
☐ other: ____

2. **If follow-up, what type?**
☐ correction
☐ additional information
☐ response to FDA request
☐ device evaluation

3. **Device evaluated by mfr?**
☐ not returned to mfr.
☐ yes ☐ evaluation summary attached
☐ no (attach page to explain why not) or provide code: ____

4. **Device manufacture date** (mo/yr)

5. **Labeled for single use?**
☐ yes ☐ no

6. **Evaluation codes** (refer to coding manual)
method ____ – ____ – ____ – ____
results ____ – ____ – ____ – ____
conclusions ____ – ____ – ____ – ____

7. **If remedial action initiated, check type**
☐ recall
☐ repair
☐ replace
☐ relabeling
☐ other: ____
☐ notification
☐ inspection
☐ patient monitoring
☐ modification/ adjustment

8. **Usage of device**
☐ initial use of device
☐ reuse
☐ unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional manufacturer narrative** and/or 11. ☐ **Corrected data**

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**DHHS Reports Clearance Office
Paperwork Reduction Project (0910-0291)
Hubert H. Humphrey Building, Room 531-H
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Washington, DC 20201**

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